

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,

Plaintiff,

v.

AMERISOURCEBERGEN CORPORATION;
AMERISOURCEBERGEN DRUG
CORPORATION; and INTEGRATED
COMMERCIALIZATION SOLUTIONS, LLC,

Defendants.

Case No. 2:22-cv-05209-GJP

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS’
MOTION TO COMPEL PRODUCTION OF INTERNAL DEA DOCUMENTS**

The core of the Government’s case is the allegation that Defendants negligently failed to report to the Drug Enforcement Administration (“DEA”) suspicious orders of controlled substances. Thus, this lawsuit centers around (1) what constitutes a suspicious order and (2) whether Defendants’ reporting decisions were reasonable (and therefore not negligent). Yet, for nearly a year, the Government has refused to produce responsive, relevant internal DEA communications on these issues. Instead, the Government insists the only relevant inquiry is what Defendants knew at the time, and DEA’s internal positions and knowledge are irrelevant to the reasonableness inquiry at the heart of the litigation. This vastly oversimplified and narrow construction of the issues is contrary to both common sense and the well-established legal definition of negligence. Moreover, it is contrary to the Court’s prior statements that evidence related to DEA, including “why the DEA did or didn’t do what they did or didn’t do,” is relevant to Defendants’ “state of mind or their culpability.” *See* Jan. 22, 2024 Tr. at 22:11-12, 26:11-12.

Defendants accordingly move to compel production of responsive, non-privileged documents in response to Defendants' First Set of Requests for Production Request Nos. 2, 3, and 12 and Defendants' Second Set of Requests for Production Request Nos. 3, 7, 8, 19, and 23.

RELEVANT FACTUAL BACKGROUND

The following facts are relevant to this Motion:

ABDC's Two-Step SOM Program: Starting in 2007, ABDC's suspicious order monitoring ("SOM") program used a two-step process, endorsed by DEA, whereby (1) a subset of placed orders were flagged as "orders of interest" and then (2) those orders of interest were reviewed by diversion control employees to determine which orders were suspicious and should be reported to DEA. In this lawsuit, the Government claims that *all* orders of interest were suspicious and should have been reported.

Defendants' and Industry Outreach to DEA on SOM Issues: There is a long, documented history of Defendants (and the entire wholesale distribution industry) seeking guidance from DEA on many aspects of suspicious order reporting, including fundamental matters like the meaning of "suspicious" (which has been roundly and consistently criticized as vague by registrants and government agencies alike). Despite being aware that the industry wanted and needed guidance (and government agencies advocated for it), DEA has consistently provided little in response.

Masters Decision: In 2017, the D.C. Circuit Court issued an opinion in *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017), an administrative action against another distributor (Masters). Defendants and the distribution industry directly sought clarification from DEA on whether *Masters* was relevant to their own ongoing regulatory compliance efforts, including the use of orders of interest. DEA either ignored such requests or confirmed that registrants should not change their SOM programs based on *Masters*. This is inconsistent with the Government's

litigation position, where thousands of the orders the Government now claims should have been reported as suspicious are so-identified only because they were flagged as orders of interest.

DEA Guidance on “Orders of Interest”: Both before and after the *Masters* decision, DEA made public and private statements confirming that two-step SOM programs using orders of interest are permissible. For instance, at a DEA conference on May 10-11, 2016, a senior attorney at DEA Chief Counsel’s Office (Dedra Curtman) told multiple distributors, including Defendants, that they did *not* need to report orders of interest as suspicious orders. *See* Ex. 1 (ABDCMDL00213400 at 401). Internal DEA communications produced by the DEA as a third-party in other opioid litigation similarly shows DEA employees discussed the [REDACTED] [REDACTED]. *See* Ex. 2 (US-DEA-00009539). This is inconsistent with the Government’s litigation position because the Government seeks to impose liability for failure to report orders of interest.

2020 Proposed Rulemaking: Starting in or around 2016, DEA informed registrants that it would provide additional clarity by way of a new suspicious order regulation. DEA did not issue this proposed rulemaking until 2020 (and it still has never been finalized). The contents of the proposed rulemaking are highly relevant to several of the above issues, including the known lack of clarity of what is a “suspicious order” and the use of orders of interest.

RELEVANT PROCEDURAL HISTORY

Defendants served Requests for Production on June 5, 2023 (“Set 1”) and June 27, 2024 (“Set 2”) seeking, among other things, documents (including internal DEA communications) related to the meaning of a “suspicious order,” guidance provided (or not provided) to Defendants on several topics, and DEA’s 2020 Notice of Proposed Rulemaking. The Government objected to producing all internal DEA communications and instead only committed to produce a subset of internal communications, based on its own view of “relevance” unrelated to Defendants’ Requests.

After a lengthy and unsuccessful conferral process, Defendants sought guidance from the Court. As set forth in Defendants' June 28, 2024 letter, the Government's limited production offer is insufficient because it turns on the Government's subjective view of relevance (most notably related to whether internal documents are relevant to objective reasonableness), which is directly at odds with Defendants' valid discovery requests. *See* ECF No. 80. And the Government relied on categorical privilege assertions, which Defendants would have no opportunity to challenge on a document-by-document basis. *See id.* On August 7, 2024, the Court issued a Memorandum Opinion encouraging the Parties to negotiate a resolution and for Defendants to file a motion to compel if those efforts were unsuccessful. *See* ECF No. 82.

The Parties have since met and conferred further. The Government confirmed during a meet and confer and in a follow-up letter dated September 20, 2024 that it would not agree to expand the scope of its limited offer of production. *See* Ex. 3 (9/20/2024 Letter from Government to Defendants). For instance, the Government will not produce internal DEA documents related to *whether* to provide Defendants guidance (*e.g.*, the Government refuses to produce internal communications regarding DEA's response to specific industry requests for guidance) or internal DEA documents related to the 2020 Notice of Proposed Rulemaking (even though DEA, as a third-party, produced a subset of documents related to this same issue in the federal opioid litigation).

RELIEF REQUESTED

Defendants respectfully request that the Court compel the Government to produce non-privileged documents responsive to the following Requests for Production (the "Requests") that relate to the following relevant topics:

Topic A: Meaning and Known Ambiguity of "Suspicious"

- **Set 1, RFP 2:** From 2014 through the filing of the complaint, all DEA Documents regarding the meaning of Suspicious Order, including but not limited to any ambiguity, vagueness, imprecision, or subjectivity in the meaning or application of the term.

- **Set 1, RFP 12:** All DEA, DOJ, OIG, GAO, and OMB Documents from 2014 through the filing of the complaint regarding the 2020 SOR Notice, including but not limited to: a. All drafts of the 2020 SOR Notice; b. All calculations of estimated times, costs, and reports of Suspicious Orders as set forth in the 2020 SOR Notice; c. the drafting, formulation, internal approvals, and issuance of the 2020 SOR Notice; d. all comments received in response to the 2020 SOR Notice and all Documents regarding such comments; e. all Communications regarding the 2020 SOR Notice with any other branch, agency, or instrumentality of the United States, including but not limited to Congress, DOJ, GAO, OIG, and OMB, and all Documents regarding such Communications; f. the timing of the issuance of the 2020 SOR Notice, including the reasons for any delays; and g. the status of the proposed rule announced by the 2020 SOR Notice.

Topic B: DEA Awareness and Acceptance of Industry Uncertainty and Lack of Guidance

- **Set 2, RFP 7:** All Documents and Communications at DEA, including internal DEA communications, related to a July 8, 2010 letter from HDMA to DEA.
- **Set 2, RFP 8:** All Documents and Communications at DEA, including internal DEA communications, related to the December 7, 2010 meeting between DEA and the Healthcare Distribution Management Association (“HDMA”), the scheduled July 31, 2013 meeting between DEA and HDMA that was cancelled by DEA, and questions the HDMA submitted to DEA on June 1, 2011 and July 2, 2013.

Topic C: DEA Position on Orders of Interest

- **Set 1, RFP 3:** From 2007 through the filing of the complaint, all DEA Documents regarding whether or how the Suspicious Order Monitoring and Reporting Obligations apply to “orders of interest” (or other similar terminology used to describe orders that hit a Registrant’s threshold, parameter, or algorithm).
- **Set 1, RFP 12:** [quoted above].
- **Set 2, RFP 19:** All Documents and Communications at DEA, including internal DEA communications, related to the DEA Distributor Conference on May 10-11, 2016.

Topic D: Relevance of *Masters* Decision to Regulatory Compliance

- **Set 2, RFP 3:** All Documents and Communications at DEA, including internal DEA communications, related to the National Association of Chain Drug Stores’ letter to DEA dated February 6, 2018 requesting clarification on the 2017 D.C. Circuit Court opinion issued in *Masters Pharmaceutical, inc. v. Drug Enforcement Administration*.
- **Set 2, RFP 23:** All Communications between DEA and Registrants regarding *In re Masters Pharm., Inc.*, 80 Fed. Reg. 55418, 55477-78 (Drug Enf’t Admin. 2015), *pet. For review denied sub nom. Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017), including all internal DEA communications regarding *Masters’* impact on Registrants’ obligations under 21 C.F.R. § 1301.74.

LEGAL STANDARD

The scope of discovery is broad. *See* Fed. R. Civ. P. 26(b)(1); *Moyer v. United Dominion Indus., Inc.*, 473 F.3d 532, 542 (3d Cir. 2007). “Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case[.]” Fed. R. Civ. P. 26(b)(1). Rule 37 provides the mechanism to compel discovery from a party who refuses to provide it. Fed. R. Civ. P. 37(a). Under Rule 37, the moving party bears the initial burden of proving the relevance of the material requested. *See Morrison v. Phila. Hous. Auth.*, 203 F.R.D. 195, 196 (E.D. Pa. 2001). If the movant meets this initial burden, the burden then shifts to the party resisting discovery to show that “the material requested does not fall within the broad scope of relevance defined by Rule 26 or is of such little relevance that the potential harm occasioned by discovery outweighs the ordinary presumption favoring its disclosure.” *First Niagara Risk Mgmt. v. Folino*, 317 F.R.D. 23, 25 (E.D. Pa. 2016).

ARGUMENT

A. Responsive Internal DEA Documents are Central to the Government’s Allegations and the Defense.

The Government’s case turns on whether Defendants negligently failed to report particular orders as suspicious. But the negligence analysis does not concern only the Defendants’ “*mens rea*,” as the Government has claimed. Instead, it relates to the care “that a ***reasonably prudent person*** would have exercised in a similar situation.” *United States v. Greene*, No. 2:17-cv-272, 2019 U.S. Dist. LEXIS 198234, at *9 (N.D. Ga. Nov. 15, 2019) (emphasis added) (addressing “negligence” under 21 U.S.C. § 842(a)(5), one of the statutes at issue here); *see id.* (“[C]ourts have routinely held that other statutory penalty provisions which include the word ‘negligence’ invoke the word’s ordinary meaning.”).

Internal DEA communications responsive to the Requests bear on the reasonableness of Defendants’ conduct. *See, e.g., United States ex rel. Poehling v. Unitedhealth Grp., Inc.*, No. CV 16-8697, 2018 U.S. Dist. LEXIS 226072, at *45 (C.D. Cal. Dec. 14, 2018) (“[A]ny documents showing that CMS’s interpretations of applicable statutes, regulations, guidance documents and contractual requirements mirrored United’s own would bear directly on the objective reasonableness of United’s interpretations.”); *SEC v. McDermott*, No. 19-4229, 2022 U.S. Dist. LEXIS 112726, at *34-35 (E.D. Pa. June 24, 2022) (internal citations omitted) (concluding that SEC internal communications were admissible because “[t]he fact that the [SEC] itself—the regulatory body charged with policing the investment adviser industry—may not have thought Defendants’ conduct untoward is relevant to whether Defendants acted reasonably”); *see also United States v. Am. Elec. Power Serv. Corp.*, No. C2-99-1182, 2001 U.S. Dist. LEXIS 18722, at *10 (S.D. Ohio Aug. 13, 2001) (defendants “entitled to conduct discovery” with respect to the EPA’s application and interpretation of regulation).¹

Defendants are entitled to defend against the Government’s allegations of unreasonable conduct by showing that their conduct was reasonable precisely because it was consistent with the actions, understanding, and guidance of DEA. For example, whether DEA officials internally approved of the use of orders of interest, or even just distinguished between orders of interest and

¹ The cases cited by the Government do not apply here because none relate to a case involving negligence as the legal standard. *See United States v. Farley*, 11 F.3d 1385 (7th Cir. 1993) (alleged violation of HSR Act did not involve negligence standard); *Consumer Fin. Prot. Bureau v. Navient Corp.*, No. 3:17-cv-101, 2018 U.S. Dist. LEXIS 76155 (M.D. Pa. May 5, 2018) (CFPB’s allegations related to unfair, deceptive, or abusive acts not involving a negligence standard); *United States ex rel. Health v. Wis. Bell*, No. 08-C-0876, 2020 U.S. Dist. LEXIS 262280 (E.D. Wis. Oct. 29, 2020) (False Claims Act case relating to whether Defendant knowingly violated the rule); *SEC v. BankAtlantic Bancorp, Inc.*, 285 F.R.D. 661 (S.D. Fla. 2012) (allegations related to Defendants knowingly, willfully, or recklessly violating securities laws); *United States v. Navistar Int’l Corp.*, 236 F. Supp. 3d 1049 (N.D. Ill. 2017) (EPA violations that did not involve negligence standard); *FTC v. Amazon.com, Inc.*, No. 2:23-cv-00932, 2024 U.S. Dist. LEXIS 150571 (W.D. Wash. Aug. 22, 2024) (FTC violations related to having actual or fairly implied knowledge).

suspicious orders without any negative commentary, bears on the reasonableness of Defendants' conduct. Or if DEA officials, in drafting the 2020 Notice of Proposed Rulemaking, acknowledged that the existing regulation was vague and that DEA had not provided registrants with sufficient guidance, that too bears on the reasonableness of Defendants' conduct.

This is far from a fishing expedition. Defendants know responsive, relevant documents exist in DEA's files because DEA produced a limited number of internal DEA documents as a third-party in the federal opioid litigation. That they refuse to do so here—where the Government is the plaintiff—is astonishing. For example, Exhibit 2 is a 2015 email discussing the [REDACTED] [REDACTED] where a DEA official emailed other officials, noting:

[REDACTED]

Ex. 2 (US-DEA-00009539) (emphasis added). This document, which would not be produced by the Government in this case under the Government's view of relevancy, shows, at a minimum, that by at least 2015 DEA was aware that the regulation needed clarity *and* that orders of interest are different from suspicious orders.

In another example, a senior DEA official [REDACTED] [REDACTED]. Ex. 4 (US-DEA-00008563). Other internal communications about this unanswered request for guidance would be highly relevant. Later, the industry asked DEA whether *Masters* outlined the reporting requirements—specifically whether all orders of interest should be reported. Ex. 5 (ABDCMDL00269677). Instead of answering this key question directly, DEA responded by pointing only to the forthcoming Notice of Proposed Rulemaking. Ex. 6 (ABDCMDL00269679). Internal

communications about whether and how to respond to this request are highly relevant here. This is especially true because, when asked directly, DEA did not tell industry that they must report all orders of interest, one of the theories of liability advanced by the Government now in this litigation. Defendants are entitled to explore issues that are squarely relevant to whether their conduct was reasonable.

B. Internal DEA Documents Responsive to the Requests Have Other Relevance.

Documents responsive to the Requests also are relevant to (1) any potential penalty assessments; (2) Defendants’ affirmative defenses; and (3) impeachment of government witnesses.

First, the documents requested are relevant to any potential penalty. In determining any penalty under 21 U.S.C. § 842(c), courts consider four factors, including “(1) the level of defendant’s culpability, [and] (2) the public harm caused by the violations.” *Advance Pharm., Inc. v. United States*, 391 F.3d 377, 399 (2d Cir. 2004). The nature and inconsistency of DEA’s guidance, confusion among DEA officials as to what constitutes a suspicious order, and conflicts between the Government’s litigation posture and prior DEA positions are all relevant to Defendants’ alleged culpability. These documents also are relevant to the “harm” caused by the alleged violations because there would be no harm caused by “failing” to report orders that DEA did not actually expect or tell Defendants to report.

Second, the documents are relevant to Defendants’ affirmative defenses, including estoppel and acquiescence. Internal DEA documents would be probative, compelling evidence to confirm Defendants’ own testimony and records that demonstrate Defendants’ reasonable reliance on DEA statements. And this Court has already recognized the potential relevance of this discovery during the January status conference. *See* Jan. 22, 2024 Tr. at 21:3-28:2.

Third, the documents are relevant impeachment evidence. *See Neuberger v. Shapiro*, No. 97-7947, 2000 U.S. Dist. LEXIS 16988, at *4 (E.D. Pa. Sept. 13, 2000) (“Indeed, witness

impeachment is a time-honored basis for discovery”); Wright & Miller, Federal Practice & Procedure, Civil 2d § 2015 (“Discovery is commonly allowed in which the discovering party seeks information with which to impeach witnesses for the opposition.”). Further, the Government has informed Defendants that it intends to retain as an expert in this case Demetra Ashley, a former DEA employee who was directly involved in responding to industry’s requests for guidance. *See* Exs. 4 (US-DEA-00008563), 5 (ABDCMDL00269677). Documents responsive to the Requests are relevant for examining and impeaching DEA officials Defendants anticipate will testify.

C. The Government’s Categorical Privilege Assertions Are Inappropriate.

The Government continues to assert that documents responsive to the Requests are privileged. But categorical assertions of privilege are not permitted and do not shield the Government from searching for and logging responsive documents on a privilege log. *See, e.g., United States v. Rockwell Int’l*, 897 F.2d 1255, 1265 (3d Cir. 1990) (“[C]laims of attorney-client privilege must be asserted document by document, rather than as a single, blanket assertion.”).

Further, to the extent the Government claims any document is protected by the deliberative process privilege, the Government bears a heavy burden for each document it claims is protected. *Redland Soccer Club v. Dep’t of the Army*, 55 F.3d 827, 854 (3d Cir. 1995); *Del. Riverkeeper Network v. Del. River Basin Comm’n*, 300 F.R.D. 207, 211 (D.N.J. 2014). Even then, that privilege is not absolute and can be challenged by Defendants. *Redland Soccer Club*, 55 F.3d at 854.

The Government cannot refuse to engage in discovery by invoking a categorical privilege claim that Defendants will be unable to challenge without the benefit of privilege log.

CONCLUSION

Defendants respectfully request the Court compel production of responsive documents to Defendants’ First Set of Requests for Production Request Nos. 2, 3, and 12 and Second Set of Requests for Production Request Nos. 3, 7, 8, 19, and 23.

Dated: November 14, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2024, I served a true and correct copy of the foregoing document via the Court's CM/ECF system.

/s/ Robert A. Nicholas
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